

CLEAN SET OF CLAIMS AS OF AUGUST 21, 2002:

- A'
- 
1. (Amended) A controlled release formulation of erythromycin A or a derivative thereof, suitable for once daily administration, comprising erythromycin from about 66% w/w to about 90% w/w of the total tablet weight and from about 0.1% to about 4% w/w of one or more pharmaceutically acceptable rate controlling polymers.

---

  2. A controlled release formulation as described in claim 1, wherein the erythromycin A derivative is clarithromycin.
  3. A controlled release formulation as described in claim 1 wherein erythromycin A or its derivative comprises about 10% w/w to about 90% w/w of the total tablet weight.
  4. A controlled release formulation as described in claim 3 wherein erythromycin A or its derivative preferably comprises about 50% w/w to about 90% w/w of the total tablet weight.
  5. A controlled release formulation described in claim 1 wherein the pharmaceutically acceptable rate controlling polymer <sup>is comprised</sup> comprises of carbohydrate gum, polyuronic acid salt, cellulose ether, acrylic acid polymer, and mixtures thereof.
  6. A controlled release formulation as described in claim 5 wherein the carbohydrate gum is selected from the group consisting of xanthan gum, tragacanth gum, gum

karaya, guar gum, acacia, gellan gum, locust bean gum, sclero gum, and mixtures thereof.

7. A controlled release formulation as described in claim 5 wherein the polyuronic acid salt is selected from the group consisting of alkali metal salts of pectic acid, alkali metal salts of alginic acid, and mixtures thereof.
8. A controlled release formulation as described in claim 7 wherein the polyuronic acid salt is preferably sodium alginate.
9. A controlled release formulation as described in claim 5 wherein the cellulose ether are selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropylcellulose, and mixtures thereof.
10. A controlled release formulation as described in claim 5 wherein the acrylic acid polymer is carbopol.

Az 11. (Amended) A monolithic controlled release formulation of clarithromycin comprising 1000 mg of clarithromycin, wherein the total weight of the dosage unit is not more than 1500 mg.

12. (Amended) A process for the preparation of a controlled release formulation of erythromycin A or a derivative thereof suitable for once daily administration comprising mixing erythromycin or a derivative thereof in an amount from about 66% w/w to about 90% w/w of the total tablet weight with about 0.1% to about 4% w/w of one or more pharmaceutically acceptable rate controlling polymers.